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END et al. disclose a process for the continuous preparation of Beta-carotene together with an emulsifier by briefly heating Beta-carotene together with an emulsifier to give a homogenous solution. The process disclosed by END et al. can be used to prepare Beta-carotene solubilizates which provide stable solutions for injection.

The CALOIANU et al. publication is a Romanian Patent. A translation of the patent is attached with this response. CALOIANU et al. disclose a nutritive cosmetic cream product. The outstanding Official Action relies on the CALOIANU et al. publication as teaching the use of 2 to 5% isopropyl myristate and 0.01 to 0.1% of vitamin E in a 0.01 to 0.05% Beta-carotene containing composition.

It is respectfully submitted that the cited publications in the outstanding Official Action fail to render obvious the claimed invention. Applicants submit that one of ordinary skill in the art would lack the motivation and the reasonable expectation of success to combine the cited publications to obtain the claimed invention.

As noted above, CALOIANU et al. disclose a cosmetic cream composition. However, KOLTER et al. and END et al. are clearly directed to Beta-carotene solubilizates which provide stable solutions for parenteral administration or injection. Applicants respectfully submit that one of ordinary skill in the art would not combine the teachings of a cream composition with

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the teachings of composition designed to be internally administered to an individual.

It is respectfully submitted that one of ordinary skill in the art would clearly appreciate that the preparation of an injectable composition must meet entirely different standards. Moreover, it is respectfully submitted that one of ordinary skill in the art would appreciate that a solution would require completely different components than a cream composition. Thus, it is believed that one of ordinary skill in the art would lack the motivation to combine CALOIANU et al. with KOLTER et al. and End et al. As such, it is respectfully submitted that the proposed combination of cited publications in the outstanding Official Action fail to render obvious the claimed invention.

In view of the present amendment and foregoing remarks, therefore, it is believed that this application is now in condition for allowance with claims 1-13 as presented. Such actions are accordingly respectfully requested.

Respectfully submitted,

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- (54) NUTRITIVE COSMETIC CREAM
- (67) Abstract: The invention relates to a nutritive cosmetic cream made up of 1 to 3 percent water-soluble atomized collugenic hydrolyzute with u moleculur weight of 3,000 to 5,000, 1 to 4 percent karité butter (Shea butter), 0.05 to 0.15 percent vitamin A, 0.01 to 0.05 percent beta carotene, 0.01 to 0.1 percent vitamin E (ulpha tocopherol), 2 to 6 percent anhydrous lunolin, 2 to 5 percent isopropyl myristate, 4 to 8 percent vegetable oil, 2 to 5 percent cetyl alcohol, 2 to 6 percent steuric acid, 0.2 to 0.5 percent preservatives, 0.2 to 0.6 percent tricthanolamine, 0.2 to 0.24 perfuning composition, and distilled water to make up 100 percent by weight. distilled water to make up 100 percent by weight.

Claims: 1

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This invention relates to a synergic cosmetic cream for maintenance of the skin.

A trophic cream has been disclosed which is made up of 1 to 2 percent crelisin (cresylene?), 2 to 3 percent cetyl alcohol, 3 to 6 percent stearin, 3 to 6 percent anhydrous lanolin, 4 to 10 percent mink oil, 5 to 7 percent vascline oil, 5 to 10 percent sclf-emulsifying emulsifier, 3 to 3.5 percent 1600 T alkyl phosphate, 1 to 1.5 percent triethanolumine, 2 to 3 percent emulgin \$ 50, 0.5 to 1 percent vitamin F, 0.03 to 0.05 percent vitamin E, 0.2 to 0.5 percent sodium benzoate, 0.2 to 0.5 percent Nipagin, 3 to 5 percent glycerin, 0.03 to 0.04 percent antioxidant, 0.4 to 0.5 percent perfume, 4 to 5 percent polyethylene glycol 400, 2.5 to 3 percent paraffin, 20 to 230 [sic] percent Dehimuls K, 20 to 25 percent vaseline, 10 to 11 percent blunched beeswax, 3 to 5 percent carrot extract, and 18 to 72 percent water.

The object of the invention is to produce a nutrient cosmetic cream by combination of an atomized soluble collagenic hydrolyzate with a synergic complex containing kurité butter (Shea butter) supplemented by vitamins A and E, a certain amount of biologically active natural substances, and a suitable fat base in a stable L-H emulsion possessing nutrient properties.

The nutritive cosmetic cream claimed for the invention is made up of 1 to 3 percent water-soluble atomized collagenic hydrolyzate with a molecular weight of 3000 to 5000, 1 to 4 percent karité butter (Shea butter), 0.05 to 0.15 percent vitamin A (1,000,000 international units), 0.01 to 0.05 percent beta carotene, 0.01 to 0.1 percent vitamin E (alpha tocopherol), 2 to 6 percent anhydrous lanolin, 2 to 5 percent isopropyl myristate, 4 to 8 percent vegetable oil, 2 to 5 percent cetyl alcohol, 2 to 6 percent stearic acid, 0.2 to 0.5 percent preservatives, 0.2 to 0.6 percent triethanolamine, 0.2 to 0.4 scenting composition, and distilled water up to 100 percent by weight.

The ability of the collagenic hydrolyzate to form complexes exerting synergle action with various natural and synthetic substances is due to its unphoteric, hipolar structure.

In the case of nutrient cream the synergic effect is exerted as a result of combination with karité butter (Shea butter), a plant fat of African origin obtained from seeds of the <u>Butyrospernum Parkii</u> tree.

Karité butter is complex in composition and has a characteristic of particular importance for pharmaceutical and cosmetic preparations, a high content, up to 11 percent, of unsuponifiable matter made up of biologically active substances. Mention is to be made of the presence of 75 percent triterpene alcohols esterified with cinammic acid which represent the basis for compatibility with the skin, natural allantoin, and vitamins A and E.

The therapeutic effects are regeneration of the skin by healing of wounds and mending of old sears, disinfection, and acceleration of healing processes. The karité butter protects intact skin from drying and some of the harmful effects of solar radiation and restores a feeling of comfort.

Combination with the collagen hydrolyzate results in synergy of nutritive, emollient, moisturizing, and stimulative action in order to keep the soluble collagen in the form of fibrils and to preserve the hydrolipidic equilibrium of the epidermis. The karité butter is at the same time also a component of the fut base of the cream, its composition including higher fatty acids in the proportion of 50 percent, including 40 percent stearic acid, 30 percent oleic acid, 5.9 percent palmitic acid, and 5 percent linoleic acid. The karité acid, 5.9 percent palmitic acid, and 5 percent linoleic acid. The karité butter may be incorporated into any type of cream; in all cases it imparts a light, fine, satiny structure producing a pleasant feeling of comfort, even in

cases of sensitive skin.

The nutrient cream claimed for the invention also contains a complement of vitamins, beta curotene (provitamin A) and vitamin E, in order to raise the percentage of natural vitamins in the karité to the level of therapeutic

The following are the advantages offered by the cream. It contains natural The following are the advantages offered by the cream. It contains natural active substances in the apeutic doses combined with an ointment base including a L-H emulsion of high penetrating power, active substances combined in a synergic complex which also incorporates a fatty base act rapidly and vigorously to restore the integrity of the skin; the natural and complementary vitamins emphasize certain properties of the collagen resulting from the activity of cellular metabolism; the reparative, cpithelializing, moisturizing, etc role is known of collagen, a biological product and principal component of conjunctive tissue, as is also its ability to be reconstituted from altered collagen as a result of reconstitution of resistant fibrils and fibers under given conditions.

Two examples of embodiment of the invention are presented in what follows.

Example 1. The following are combined in order to obtain 100 g of cream: 2 g collagenic hydrolyzate; 4 g karité butter supplemented by 0.1 g beta carotene, 0.1 g vitumin A (1,000,000 tU/g), 0.05 vitamin E, 5 g anhydrous lanolin, 8 g plant oil, 4 g stearin, 2 g cetyl alcohol, 3 g isopropyl nyristate, 0.3 g preservatives, 0.3 g triethanolamine, 0.2 g perfuming composition, and distilled water to make up 100 g.

The production process consists of melting the lipid substances in an enameled capsule on a water bath heated to 70 to 80 °C. The preservatives are dissolved, and then the amount of water necessary, simultaneously heated to 70 to 80 °C, is added, in which capsule the collagenic hydrolyzate is dissolved. The two phases are emulsified by neutralization, pH = 6 to 6.5, and mixing is continued until the temperature reaches 30 to 35 °C, at which time the vitamin supplement is added; mixing is carried out to homogenization and the mixture is perfumed. is perfuned.

The cream obtained is homogeneous and has a smooth, shiny surface light yellow in color; the pII = 6 to 6.5.

Example 2. The following are combined in order to obtain 100 g cream: 1.5 g collagenic hydrolyzate; 0.5 g beta carotene, 0.05 g vitamin A (1,000,000 l.U./g), 0.05 g vitamin E, 4 g anhydrous lanolin, 6 g plant oil, 3 g cetyl alcohol, 3 g stearic acid, 4 g isopropyl myristate, 0.3 preservatives, 0.2 g triethanolamine, 0.2 g perfuming composition, and distilled water to make up 100 g.

The production process is that described in Example 1. The cream obtained is physicochemically and microbiologically stable.

Stability of the emulsion and efficuery of treatment are ensured by the type of 1.-II commission, which permits rapid penetration of the skin by the cream, an effect enhanced by the synergism achieved by combining the components selected.

Claim

A nutritive cosmetic creum based on collagen, characterized in that such cream is made up of 1.3 percent water-soluble atomized collagenic hydrolyzate with a molecular weight of 3,000 to 5,000, 1 to 4 percent karité butter (Shea butter), 0.05 to 0.15 percent 1,000,000 IU vitamin A, 0.01 to 0.05 percent beta carotene, 0.01 to 0.1 percent vitamin E (alpha tocopherol),

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2 to 6 percent anhydrous landlin, 2 to 5 percent isopropyl myristate, 4 to 8 percent plant oil, 2 to 5 percent cetyl alcohol, 2 to 6 percent stearic acid, 0.2 to 0.5 percent preservatives, 0.2 to 0.8 percent triethanolamine, 0.2 to 0.4 percent perfuming composition, and distilled water to make up 100 percent by weight.

Chairperson of Examining Commission: Elena Pentelescu, pharmaceutical chemist Examiner: Dolna Anghel, pharmaceutical chemist